REMARKS

Claims 1-20 and 22-42 are pending. Claims 1-18 are allowed. Claims 19-43 stand rejected.

Claims 1, 19-22, 29, 31, 36-38 and 43 have been amended to more accurately reflect the claimed invention. Claims 21 and 43 have been cancelled. Support for the amendment of claim 1, 19, 20, 21, 22, 29, 31, 36-38 and 43 can be found in the specification in the originally filed claims and page 6, line 8 through page 7, line 30. No new matter has been added.

Pending claims 1-20 and 22-42 considered together with the following remarks are believed sufficient to place the application into condition for allowance. Accordingly, an early and favorable action on the merits is earnestly solicited.

Interview Summary

Applicants note with appreciation that Examiner Ethan Whisenant conducted a personal Interview with Applicants' representative, Dr. Eggerton Campbell, on November 17, 2008. Examiner Whisenant was very helpful in clarifying the outstanding issues.

During the Interview, Dr. Campbell presented Examiner Whisenant with a copy of proposed amendments which are believed to overcome the outstanding rejections. Applicants' representative reviewed each and every issue raised under 35 U.S.C. § 112, second paragraph and explained how the proposed amendment would overcome the indefiniteness rejections.

Sequentially, Applicants' representative explained that the prior art reference (Mori *et al*) does not teach or suggest an apparatus, kit and method steps for selective separation and purification of RNA or DNA.

Additionally it was argued that Mori et al., compared to the present invention, does not teach an apparatus with the properties required for selective separation and purification in a nucleic acid-absorbing porous membrane as claimed. The Examiner understands the limitations of the Mori et al. reference and agreed to reconsider all previous rejections. Although the Examiner looked upon Applicants' response with favor during the Interview, the Examiner was not willing to withdraw the rejections without further consideration.

Furthermore, the structural differences between the present invention and the closest prior art of Mori *et al.* in regards to the nucleic acid-absorbing porous membrane and washing solutions were discussed. In addition, the advantages of the selective separation and purification from a mixture of nucleic acids were discussed.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 20-43 stand rejected under 35 U.S.C. § 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Reconsideration of the above rejection is respectfully requested based on the following considerations.

The Examiner states that claims 20-21 and 43 are indefinite because it is unclear what structural limitations are imparted by the limitation "automatically".

In response to the rejection, claims 20-21 and 43 have been amended to recite that the apparatus for selective separation of RNA (claims 20-21), DNA or RNA (claim 43) wherein the apparatus further comprises a means for automating the sequential steps to achieve selective

separation of RNA or DNA.

The Examiner states that claim 22 is indefinite because there is no nexus between the preamble and the claim steps.

In response to the rejection, claim 22 has been amended to recite that the final step results in "the separated and purified RNA or DNA" and provides a nexus between the preamble and the claimed method steps.

The Examiner states that claim 31 is indefinite for reciting a typographical error and for reciting only "RNA" and not "DNA or RNA" as set forth in prior claims from which claim 31 depends upon.

In response to the rejection, claim 31 has been amended to recite "the method for selectively separating and purifying RNA or DNA according to claim 28.

The Examiner states that claims 22 and 28 are indefinite because there is no nexus between the preamble and the claim steps.

In response to the rejection, claims 22 and 28 have been amended referring back to separating and purifying the final product.

Based on the above-amendment to the claims, the claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Withdrawal of the rejections are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 22-25, 28-30, and 32-41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by **Mori *et al.* (US 2003/0170664)**. It appears the Examiner could have rejected the claims under 35 U.S.C. § 102(b) as well.

Reconsideration of the above rejection is respectfully requested based on the following considerations.

The Present Invention

The present invention is drawn to an apparatus, kit and method steps for selective separation and purification of DNA or RNA.

Distinctions Over the Cited Reference

Mori *et al.* (US 2003/0170664)

The Examiner believes that Mori *et al.* is relevant for teaching the concept of purifying nucleic acids by absorption and desorption of a porous membrane in a container.

However, Mori *et al.* does not disclose the differences in absorption and desorption of DNA vs. RNA by washing the porous membranes with various amounts of water-soluble organic solvents which achieves selective adsorbsion and desorbsion of either RNA or DNA combined with the claimed nucleic acid-absorbing porous membrane. The changes in the amount of water-soluble organic solvent in the buffers results in the preferential purification of either RNA or DNA. This is evidenced in Figure 7 of the present specification. The Examiner is reminded that claims 22-25, 28-30, and 32-41 are all drawn to either selective separation and purification of

RNA or DNA (**not both**). Thus, the present invention provides an easy and inexpensive method of selective separation and purification of either DNA or RNA from a solution of mixture containing both DNA and RNA. The principle applied to said selective separation based of different affinities to the porous membranes augmented by the makeup of the washing buffers is novel. Mori *et al.* fails to teach the claimed method steps, apparatus and kits combining selective methods for separation and purification of RNA or DNA (**not both**). Mori *et al.* also fails to teach the combination of water-soluble organic solvent in the buffers results in the preferential purification of either RNA or DNA with an apparatus comprising a nucleic acid-absorbing porous membrane for selective separation and purification.

Legal Standard For Anticipation

The standard for a rejection under 35 U.S.C. § 102(b) is established in MPEP §2131. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. If an independent claim is allowable under 35 U.S.C. § 102, then any claim depending therefrom is also allowable.

Therefore, it is submitted that Mori *et al.* (US 2003/0170664) does not teach each and every limitation of the present claimed invention.

Accordingly, the present invention is *not* anticipated by the Mori *et al.* (US 2003/0170664) reference of record. Any contention of the USPTO to the contrary must be reconsidered at present.

Issues Under 35 U.S.C. § 103(a) Obviousness

Claim 31 stands rejected under 35 U.S.C. § 103(a) as being obvious over Mori *et al.* (US 2003/0170664).

Claims 19-21, and 42-43 stand rejected under 35 U.S.C. § 103(a) as being obvious over Mori *et al.* (US 2003/0170664) in view of Stratagene Catalog (1988; page 39).

Reconsideration of the above rejection is respectfully requested based on the following considerations.

Distinctions Over the Cited Reference

Mori *et al.* (US 2003/0170664)

Applicants contend that the arguments described above with respect to distinctions over the Mori *et al.* reference is equally applicable here (and are incorporated herein by reference in their entirety).

Strategene Catalog

The Examiner applies the Strategene Catalog for the teach of the advantages of assembling a kit.

Therefore, the additional cited art of the Strategene Catalog is incapable of curing the above noted deficiencies of Mori *et al.*, and thus are incapable of rendering the instant invention as claimed obvious.

Legal Standard for Determining Prima Facie Obviousness

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper.

The rationale should be made explicit, *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), and the Examiner must interpret the reference as a whole and cannot pick and choose only those selective portions of the reference which support the Examiner's position. *In re Fine,* 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.").

As the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP § 2143.03.

MPEP § 2143.03 recites examples of Basic Requirements of a *Prima Facie* Case of Obviousness and seven exemplary rationales.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

However, Applicants fully address these rationales below. According to Applicants analysis below, the Examiner has not met the basic requirements of a *prima facie* case of obviousness. More specifically, Applicants contend that:

(A) Combining prior art elements according to known methods cited do not yield predictable results for an apparatus for selective separation and purification of DNA or RNA combined with the claimed buffers;

(B) Simple substitution of one known apparatus for nucleic acids, does not yield predictable results in regards to an apparatus for selective separation and purification of DNA or RNA;

(C) There is no known technique to improve an apparatus which would one skilled in the art to use the claimed buffers, and in particular, incorporate these buffers with an apparatus for selective separation and purification of DNA or RNA;

(D) Applying known techniques as taught by Mori *et al.* and the Strategene Catalog do not yield predictable results for said apparatus for selective separation and purification of DNA or RNA as claimed;

(E) The Examiner cannot support the conclusion of "obviousness" on the basis "Obvious to try" – there are no predictable methods or models cited by the Examiner that establish a reasonable expectation of success for said methods considering that it was not known how the claimed apparatus and buffers would interact in the methods of selective separation and purification of DNA or RNA as claimed;

(F) There is no reason or rationale cited by the Examiner that may prompt variations from the disclosure of Mori *et al.* and the Strategene Catalog that would result in the claimed methods of selective separation and purification of DNA or RNA;

(G) There is no proper teaching, suggestion, motivation, and/or reasonable expectation of success that would yield predictable results in the prior art as cited by the Examiner that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed methods, kits and apparatus for selective separation and purification of DNA or RNA combined with the claimed buffers.

Overall, as discussed above, Mori *et al.* fail to disclose the instantly claimed apparatus, kit and method steps for selective separation and purification of DNA or RNA combined with the claimed buffers, and this feature has not properly accounted for in the Office Action. The cited secondary references fail to cure the deficiencies of the primary reference. Accordingly, the present invention is ***not*** rendered obvious in view of the teachings and disclosures of the cited modification of Mori *et al.* and the further combination of the Strategene Catalog. Any contentions of the USPTO to the contrary must be reconsidered at present.

The Examiner is reminded that claims 1-18 are allowable over the prior art of record.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eggerton A. Campbell, Reg. No. 51,307, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: December 19, 2008

Respectfully submitted,

By _____

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